ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lotimax 56 mg chewable tablets for dogs (1.3–2.5 kg)
Lotimax 112 mg chewable tablets for dogs (>2.5–5.5 kg)
Lotimax 225 mg chewable tablets for dogs (>5.5–11 kg)
Lotimax 450 mg chewable tablets for dogs (>11–22 kg)
Lotimax 900 mg chewable tablets for dogs (>22–45 kg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance :
Each chewable tablet contains:

Lotimax chewable tablets	**lotilaner (mg)**
for dogs (1.3–2.5 kg)	56.25
for dogs (>2.5–5.5 kg)	112.5
for dogs (>5.5–11 kg)	225
for dogs (>11–22 kg)	450
for dogs (>22–45 kg)	900

Excipients:

Qualitative composition of excipients and other constituents
Cellulose, powdered
Lactose monohydrate
Silicified microcrystalline cellulose
Meat dry flavour
Crospovidone
Povidone K30
Sodium laurilsulfate
Silica, colloidal anhydrous
Magnesium stearate

White to beige round chewable tablets with brownish spots.

3. CLINICAL INFORMATION

3.1 Target species

Dogs

3.2 Indications for use for each target species

For the treatment of flea and tick infestations in dogs.

This veterinary medicinal product provides immediate and persistent killing activity for 1 month for fleas (*Ctenocephalides felis* and *C. canis*) and ticks (*Rhipicephalus sanguineus, Ixodes ricinus, I. hexagonus and Dermacentor reticulatus*).

Fleas and ticks must attach to the host and commence feeding in order to be exposed to the active substance.

The veterinary medicinal product can be used as part of a treatment strategy for the control of flea allergy dermatitis (FAD).

For the treatment of demodicosis (caused by *Demodex canis*).

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

Parasites need to start feeding on the host to become exposed to lotilaner; therefore the risk of the transmission of parasite borne diseases cannot be completely excluded.

3.5 Special precautions for use

Special precautions for safe use in the target species:

All safety and efficacy data have been acquired from dogs and puppies 8 weeks of age and older and 1.3 kg of body weight and greater. Use of this veterinary medicinal product in puppies younger than 8 weeks of age or less than 1.3 kg of body weight should be based on a benefit-risk assessment by the responsible veterinarian.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Wash hands after handling the product.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Target species: Dogs

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Diarrhoea[1,2], Bloody diarrhoea[1], Vomiting[1,2]; Anorexia[1,2], Lethargy[2], Polydipsia[1,2]; Ataxia[3], Convulsion[3], Tremor[3]; Pruritus[1,2]; Inappropriate urination[1], Polyuria[1,2], Urinary incontinence[1,2]

[1] Mild and transient
[2] Typically resolve without treatment
[3] Transient in most cases

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy, lactation or in breeding dogs.

Pregnancy and lactation:

Use only according to the benefit/risk assessment by the responsible veterinarian.
Laboratory studies in rats have not produced any evidence of teratogenic effects or any adverse effect on the reproductive capacity of males and females.

3.8 Interaction with other medicinal products and other forms of interaction

None known.
During clinical testing, no interactions between lotilaner and routinely used veterinary medicinal products were observed.

3.9 Administration routes and dosage

For oral use.

The veterinary medicinal product should be administered in accordance with the following table to ensure a dose of 20 to 43 mg lotilaner/kg bodyweight.

Body weight of dog (kg)	**Strength and number of tablets to be administered**				
	Lotimax 56 mg	Lotimax 112 mg	Lotimax 225 mg	Lotimax 450 mg	Lotimax 900 mg
1.3–2.5	1				
>2.5–5.5		1			
>5.5–11.0			1		
>11.0–22.0				1	
>22.0–45.0					1
>45	Appropriate combination of tablets				

Use an appropriate combination of available strengths to achieve the recommended dose of 20– 43 mg/kg.

Lotimax is a palatable chewable flavoured tablet. Administer the chewable tablet(s) monthly with or after food.

For the treatment of demodicosis (caused by *Demodex canis*):
Monthly administration of the product for two consecutive months is efficacious and leads to a marked improvement of clinical signs. Treatment should be continued until two negative skin scrapings are obtained one month apart. Severe cases may require prolonged monthly treatments. As demodicosis is a multi-factorial disease, where possible, it is advisable to also treat any underlying disease appropriately.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse reactions were observed following oral administration to puppies aged 8–9 weeks and weighing 1.3–3.6 kg treated with overdoses of up to 5 times the maximum recommended dose (43 mg, 129 mg and 215 mg lotilaner/kg bodyweight) on eight occasions at monthly intervals.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP53BE04

4.2 Pharmacodynamics

Lotilaner, a pure enantiomer from the isoxazoline class is active against fleas (*Ctenocephalides felis* and *Ctenocephalides canis*), - the tick species *Dermacentor reticulatus, Ixodes hexagonus, Ixodes ricinus and Rhipicephalus sanguineus* as well as *Demodex canis* mites.

Lotilaner is a potent inhibitor of gamma–aminobutyric acid (GABA)-gated chloride channels, resulting in rapid death of ticks and fleas. The activity of lotilaner was not affected by resistance to organochlorines (cyclodienes, e.g. dieldrin), phenylpyrazoles (e.g. fipronil), neonicotinoids (e.g. imidacloprid), formamidines (e.g. amitraz) and pyrethroids (e.g. cypermethrin).

For fleas, the onset of efficacy is within 4 hours of attachment for one month after product administration. Fleas on the animal prior to administration are killed within 6 hours.
For ticks, the onset of efficacy is within 48 hours of attachment for one month after product administration. Existing *I. ricinus* ticks on the animal prior to administration are killed within 8 hours.

The veterinary medicinal product kills existing and newly emerged fleas on dogs before they can lay eggs. Therefore, the product breaks the flea life cycle and prevents environmental flea contamination in areas to which the dog has access.

4.3 Pharmacokinetics

Following oral administration, lotilaner is readily absorbed and peak blood concentration is reached within 2 hours. Food enhances the absorption. The terminal half-life is approximately 4 weeks. This long terminal half-life provides effective blood concentrations for the entire duration of the inter-dosing interval.
The major route of elimination is biliary excretion and renal excretion is the minor route of elimination (less than 10% of the dose). Lotilaner is metabolized to a small extent into more hydrophilic compounds which are observed in faeces and urine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

The tablets are packaged in aluminium/aluminium blisters packaged into an outer cardboard box. Each tablet strength is available in pack sizes of 3 tablets.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/24/311/001-005

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 25/04/2024.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lotimax 56 mg chewable tablets for dogs (1.3–2.5 kg)
Lotimax 112 mg chewable tablets for dogs (>2.5–5.5 kg)
Lotimax 225 mg chewable tablets for dogs (>5.5–11 kg)
Lotimax 450 mg chewable tablets for dogs (>11–22 kg)
Lotimax 900 mg chewable tablets for dogs (>22–45 kg)

2. STATEMENT OF ACTIVE SUBSTANCES

56 mg lotilaner
112 mg lotilaner
225 mg lotilaner
450 mg lotilaner
900 mg lotilaner

3. PACKAGE SIZE

3 tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.
Administer with or after food.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

14. MARKETING AUTHORISATION NUMBERS

EU/2/24/311/001 (56 mg lotilaner; 3 chewable tablets)
EU/2/24/311/002 (112 mg lotilaner; 3 chewable tablets)
EU/2/24/311/003 (225 mg lotilaner; 3 chewable tablets)
EU/2/24/311/004 (450 mg lotilaner; 3 chewable tablets)
EU/2/24/311/005 (900 mg lotilaner; 3 chewable tablets)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BLISTERS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lotimax

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

56 mg lotilaner
112 mg lotilaner
225 mg lotilaner
450 mg lotilaner
900 mg lotilaner

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Lotimax 56 mg chewable tablets for dogs (1.3–2.5 kg)
Lotimax 112 mg chewable tablets for dogs (>2.5–5.5 kg)
Lotimax 225 mg chewable tablets for dogs (>5.5–11 kg)
Lotimax 450 mg chewable tablets for dogs (>11–22 kg)
Lotimax 900 mg chewable tablets for dogs (>22–45 kg)

2. Composition

Each chewable tablet contains:

Lotimax chewable tablets	lotilaner (mg)
for dogs (1.3–2.5 kg)	56.25
for dogs (>2.5–5.5 kg)	112.5
for dogs (>5.5–11 kg)	225
for dogs (>11–22 kg)	450
for dogs (>22–45 kg)	900

White to beige round chewable tablets with brownish spots.

3. Target species

Dogs

4. Indications for use

Treatment of flea and tick infestations in dogs.

This veterinary medicinal product provides immediate and persistent killing activity for 1 month for fleas (*Ctenocephalides felis* and *C. canis*) and ticks (*Rhipicephalus sanguineus, Ixodes ricinus, I. hexagonus, and Dermacentor reticulatus*).

Fleas and ticks must attach to the host and commence feeding in order to be exposed to the active substance.

The product can be used as part of a treatment strategy for the control of flea allergy dermatitis (FAD).

For the treatment of demodicosis (caused by *Demodex canis*).

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:

Parasites need to start feeding on the host to become exposed to lotilaner; therefore the risk of the transmission of parasite borne diseases cannot be completely excluded.

Special precautions for safe use in the target species:
All safety and efficacy data have been acquired from dogs and puppies 8 weeks of age and older and 1.3 kg of body weight and greater. The administration of this product in puppies younger than 8 weeks of age or less than 1.3 kg of body weight should be based on a benefit-risk assessment by the responsible veterinarian.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands after handling the product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or label to the physician.

Pregnancy and lactation:
Laboratory studies in rats have not produced any evidence of teratogenic effects.
The safety of the veterinary medicinal product has not been established during pregnancy or lactation. Use only according to the benefit/risk assessment by the responsible veterinarian.

Fertility:
Laboratory studies in rats have not produced any evidence of any adverse effect on the reproductive capacity of males and females.
The safety of the veterinary medicinal product has not been established in breeding dogs. Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
None known. During clinical testing, no interactions between lotilaner and routinely used veterinary medicinal products were observed.

Overdose:
No adverse reactions were observed following oral administration to puppies aged 8–9 weeks and weighing 1.3–3.6 kg treated with overdoses of up to 5 times the maximum recommended dose (43 mg, 129 mg and 215 mg lotilaner/kg bodyweight) on eight occasions at monthly intervals.

7. Adverse events

Target species: Dogs

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Diarrhoea[1,2], Bloody diarrhoea[1], Vomiting[1,2]; Anorexia[1,2], Lethargy[2], Polydipsia (increased thirst)[1,2]; Ataxia[3], Convulsion[3], Tremor[3]; Pruritus (itching)[1,2]; Inappropriate urination[1], Polyuria (increased urination)[1,2], Urinary incontinence[1,2]

[1] Mild and transient
[2] Typically resolve without treatment
[3] Transient in most cases

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report

any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

For oral use.

The veterinary medicinal product should be administered in accordance with the following table to ensure a dose of 20 to 43 mg lotilaner/kg bodyweight.

Body weight of dog (kg)	**Strength and number of tablets to be administered**				
	Lotimax 56 mg	Lotimax 112 mg	Lotimax 225 mg	Lotimax 450 mg	Lotimax 900 mg
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>2.5–5.5		1			
>5.5–11.0			1		
>11.0–22.0				1	
>22.0–45.0					1
>45	Appropriate combination of tablets				

Use an appropriate combination of available strengths to achieve the recommended dose of 20–43 mg/kg.

For the treatment of demodicosis (caused by *Demodex canis*):
Monthly administration of the product for two consecutive months is efficacious and leads to a marked improvement of clinical signs. Treatment should be continued until two negative skin scrapings are obtained one month apart. Severe cases may require prolonged monthly treatments. As demodicosis is a multi-factorial disease, where possible, it is advisable to also treat any underlying disease appropriately.

9. Advice on correct administration

Lotimax is a palatable chewable flavoured tablet. Administer the chewable tablet(s) monthly with or after food.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and blister after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/24/311/001-005

The tablets are packaged in aluminium/aluminium blisters packaged into an outer cardboard box. Each tablet strength is available in pack sizes of 3 tablets.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

16. Contact details

Marketing authorisation holder:
Elanco GmbH, Heinz-Lohmann-Str. 4, 27472 Cuxhaven, Germany

Manufacturer responsible for batch release:
Elanco France S.A.S., 26 rue de la Chapelle, 68330 Huningue, France

Local representatives and contact details to report suspected adverse reactions:
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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17. Other information

Lotilaner, a pure enantiomer from the isoxazoline class is active against fleas (*Ctenocephalides felis* and *Ctenocephalides canis*), - the tick species *Dermacentor reticulatus, Ixodes hexagonus, Ixodes ricinus and Rhipicephalus sanguineus* as well as *Demodex canis* mites.

Lotilaner is a potent inhibitor of gamma–aminobutyric acid (GABA)-gated chloride channels, resulting in rapid death of ticks and fleas. The activity of lotilaner was not affected by resistance to organochlorines (cyclodienes, e.g. dieldrin), phenylpyrazoles (e.g. fipronil), neonicotinoids (e.g. imidacloprid), formamidines (e.g. amitraz) and pyrethroids (e.g. cypermethrin).

For fleas, the onset of efficacy is within 4 hours of attachment for one month after product administration. Fleas on the animal prior to administration are killed within 6 hours.

For ticks, the onset of efficacy is within 48 hours of attachment for one month after product administration. Existing *I. ricinus* ticks on the animal prior to administration are killed within 8 hours.

The veterinary medicinal product kills existing and newly emerged fleas on dogs before they can lay eggs. Therefore, the product breaks the flea life cycle and prevents environmental flea contamination in areas to which the dog has access.